

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

DMB  
Display Date 4-9-02  
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Certifier R. LEDESMA

**Implantation or Injectable Dosage Form New Animal Drugs; Ketamine Hydrochloride**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Vetrepharm Research, Inc. The ANADA provides for veterinary prescription use of an injectable solution of ketamine hydrochloride in cats and subhuman primates.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

**SUPPLEMENTARY INFORMATION:** Vetrepharm Research, Inc., 119 Rowe Rd., Athens, GA 30601, filed ANADA 200-257 that provides for veterinary prescription use of Ketamine HCL, an injectable solution of ketamine hydrochloride, in cats and subhuman primates for restraint.

ANADA 200-257 is approved as of November 9, 2001, and the regulations are amended in 21 CFR 522.1222a to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Vetrepharm Research, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for this sponsor.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

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approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

### **List of Subjects**

#### *21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

#### *21 CFR Part 522*

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

### **PART 510—NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for “Vetrepharm Research, Inc.” and in the table in paragraph (c)(2) by numerically adding an entry for “064847” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * * * *	* * *
Vetrepharm Research, Inc., 119 Rowe Rd., Athens, GA 30601 .....	064847
* * * * *	* * *

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	* * * * *
064847 .....	Vetrepharm Research, Inc., 119 Rowe Rd., Athens, GA 30601
* * * * *	* * * * *

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

3. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

4. Section 522.1222a is revised to read as follows:

**§ 522.1222a Ketamine.**

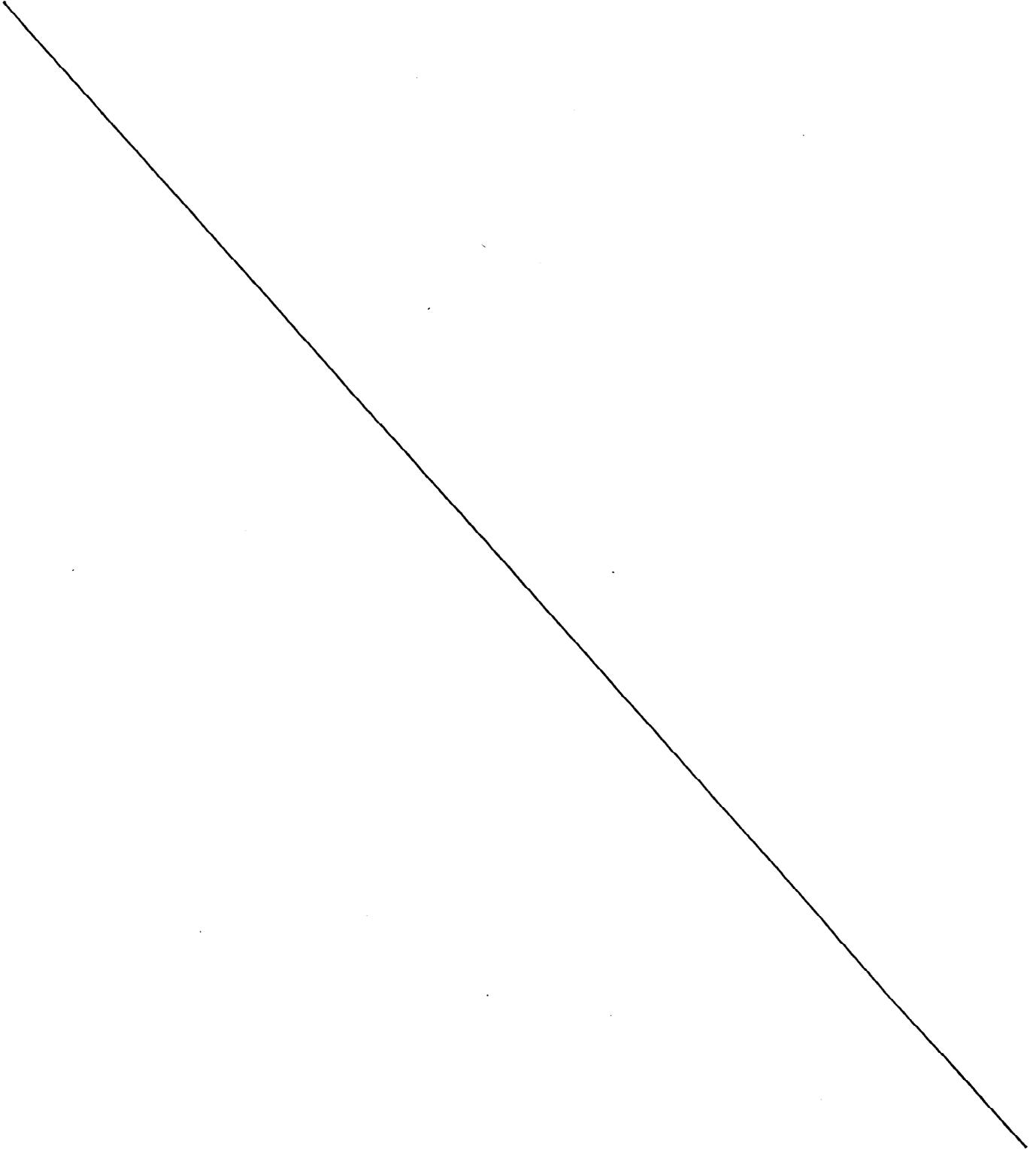
(a) *Specifications.* Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) *Sponsors.* See Nos. 000010, 000074, 000856, 059130, 061690, 064408, and 064847 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Cats*—(i) *Amount*. 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(ii) *Indications for use*. For restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.



(2) *Subhuman primates*—(i) *Amount*. 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

(ii) *Indications for use*. For restraint.

Dated: 2/27/02

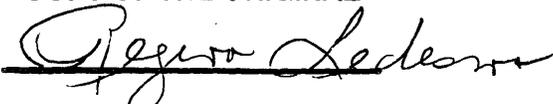
February 27, 2002.

  
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Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

  
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Regina Sedesma